

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
UNITED STATES DISTRICT COURT**DISTRICT OF NEVADA**BARBARA HEINRICH and GREGORY
HEINRICH,

Plaintiffs

v.

ETHICON, INC.; ETHICON LLC; and
JOHNSON & JOHNSON,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

**Order Denying Motion to Exclude Opinion
of Ja-Hong Kim****[ECF No. 47]**

This case was part of multidistrict litigation (MDL) assigned to the United States District Court for the Southern District of West Virginia concerning the use of transvaginal surgical mesh to treat stress urinary incontinence (SUI). Plaintiff Barbara Heinrich alleges that she suffered injuries after having the TVT-SECUR (TVT-S) product implanted. The TVT-S was designed and manufactured by defendants Johnson & Johnson and Ethicon, Inc. ECF No. 4. This case was recently remanded from the MDL court with several motions pending.

The defendants move to exclude the testimony of Dr. Ja-Hong Kim regarding the state of mind of Heinrich's implanting surgeon, Dr. Hsieh, and what Dr. Hsieh knew when he advised Heinrich of the risks and benefits of TVT-S. The defendants argue this testimony is unreliable, irrelevant, and unfairly prejudicial. They contend that Dr. Hsieh is best suited to testify to his own state of mind, what he knew at the time, and what he would have told Heinrich about the product.

The plaintiffs respond that Dr. Kim will not testify about Dr. Hsieh's state of mind. Rather, she will testify about what a urologist considers when weighing the risks and benefits of selecting a particular procedure or product to treat SUI. The plaintiffs contend that as a

1 urologist, Dr. Kim is qualified to opine that the defendants' failure to advise physicians of TVT-
2 S's increased failure rate deprived physicians, including Dr. Hsieh, of information needed to
3 make an informed risk/benefit analysis. The plaintiffs contend Dr. Hsieh testified that he was
4 unaware of increased failure rates associated with the TVT-S and that he would have reviewed
5 that information if it had been given to him.

6 The parties adopt Judge Goodwin's prior articulation of the standard for reviewing
7 motions challenging expert testimony under Federal Rule of Evidence 702 and *Daubert v.*
8 *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), so I do the same. *See Huskey v.*
9 *Ethicon, Inc.*, 29 F. Supp. 3d 691, 701-02 (S.D.W. Va. 2014); *Edwards v. Ethicon, Inc.*, No.
10 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

11 The defendants challenge the following paragraph of Dr. Kim's expert report:

12 For these reasons, Ethicon failed to advise Mrs. Heinrich's implanting physician
13 of the adverse events and risks associated with the TVT-S. While Dr. Yakaitis
14 consented Mrs. Heinrich for the procedure, she could not have properly done so
15 because she was not fully aware of the adverse events and risks of the TVT-S. In
16 addition, if Dr. Hsieh [sic] or Dr. Yakaitis had been made aware of the increased
17 risk of failure of the TVT-S, either one could have made a choice to use a more
18 studied device. Because Ethicon had knowledge of these risks, they should have
19 included them in the [Instructions for Use (IFU)], so that Dr. Yakaitis or Dr.
20 Hsieh could perform an appropriate risk-benefit analysis.

21 ECF No. 47-1 at 23.

22 I deny the defendants' motion because Dr. Kim does not purport to opine on Dr.
23 Hsieh's state of mind. Instead, she opines that the TVT-S product had a higher risk of
failure, that the defendants failed to advise physicians of this risk, and as a result, Dr.
Hsieh (like any other physician) lacked information to perform a comprehensive
risk/benefit analysis of using this particular product as opposed to some other product or
procedure. As an experienced urologist who has performed over 300 complex pelvic

1 reconstruction surgeries following complications from mesh implants, Dr. Kim may
2 testify “about the risks [she] perceives that the [TVT-S] poses to patients and then opine
3 the [TVT-S] IFU did not convey those risks.” *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-
4 01378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015); *see also* ECF No. 58-1 (Dr.
5 Kim’s expert report detailing her qualifications and experience). Dr. Hsieh’s knowledge
6 and state of mind do not affect Dr. Kim’s qualifications to offer an opinion regarding the
7 product’s alleged increased risks and the defendants’ alleged failure to inform physicians
8 of those risks. The defendants do not challenge Dr. Kim’s qualifications to render the
9 opinions she offers. Consequently, I deny the defendants’ motion.

10 I THEREFORE ORDER that the defendants’ motion to exclude the testimony of Ja-Hong
11 Kim (**ECF No. 47**) is **DENIED**.

12 DATED this 17th day of April, 2020.



14 ANDREW P. GORDON
15 UNITED STATES DISTRICT JUDGE
16
17
18
19
20
21
22
23